



DUKE UNIVERSITY MEDICAL CENTER

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Division of Orthopaedic Surgery

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Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

To Whom It May Concern:

I reference Document No. 97N-484S.

I would be opposed to any FDA regulation that would require clinical trials and lengthy regulatory documents regarding the use of bone products.

At the present time, it seems that it would limit valuable utilization of these bone products for appropriate patient care and benefit.

I recognize the role of the FDA regulating tissue safety for patients. However, I think there are appropriate guidelines and regulations in place.

Your consideration is most appreciated.

Yours very truly,

Stephen N. Lang, M.D.

SNL:ld

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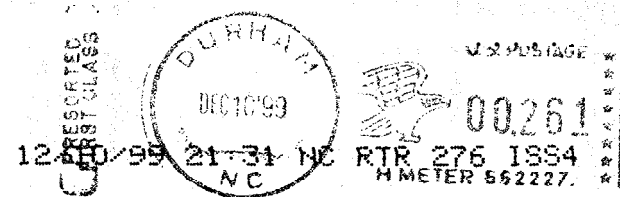


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